

**Department of Health and Human Services
National Institute of Environmental Health Sciences
National Cancer Institute**

**Minutes of the Research Process Subcommittee of the Interagency Breast Cancer and
Environmental Research Coordinating Committee**

June 20, 2011

The Research Process Subcommittee of the Interagency Breast Cancer and Environmental Research Coordinating Committee was convened for a meeting on June 20, 2011 at 1:00 p.m. via webinar. The Chair of the subcommittee is Michael Gould, PhD of the University of Wisconsin.

Subcommittee Members Present

Sally Darney, PhD
Michael Gould, PhD
Laura Nikolaides, MS
Kenneth Portier, PhD
Gayle Vaday, PhD
Cheryl Walker, PhD

NIH Staff Present

Jennifer Collins, MR
Nonye Harvey, MPH

I. Background

The Interagency Breast Cancer and Environmental Research Coordinating Committee (IBCERCC) is a congressionally mandated body established by the National Institute of Environmental Health Sciences (NIEHS), in collaboration with the National Cancer Institute (NCI). This Committee is comprised of 19 voting members, including representatives of Federal agencies; non-federal scientists, physicians, and other health professionals from clinical, basic, and public health sciences; and advocates for individuals with breast cancer.

The Committee's primary mission is to facilitate the efficient and effective exchange of information on breast cancer research activities among the member agencies, and to advise the NIH and other Federal agencies in the solicitation of proposals for collaborative, multidisciplinary research, including proposals to further evaluate environmental and genomic factors that may be related to the etiology of breast cancer. The Committee serves as a forum and assists in increasing public understanding of the member agencies' activities, programs, policies, and research, and in bringing important matters of interest forward for discussion.

The objectives of the Research Process (RP) Subcommittee of the IBCERCC are integrated and dependent on the objectives and activities of the other Subcommittees of the IBCERCC and include the following: to set research priorities (based on work of the State-of-the-Science Subcommittee), to decrease redundancies across federal and non-governmental organizations, to develop a process for soliciting research, to foster collaborations (based on the work of the Research Translation,

Dissemination, and Policy Implications Subcommittee), to highlight peer review issues, and to identify most appropriate models for agencies to work together.

The IBCERCC RP Subcommittee held its seventh meeting, hosted by NIEHS and the NCI, via webinar on June 20, 2011 beginning at 1:00 p.m. Attendees of the meeting included Subcommittee members and NIH staff. The meeting agenda included a review of the minutes from the RP breakout sessions at the May 12-13, 2011 IBCERCC meeting and progress updates on the funding models, portfolio analysis, and recommendations chapters.

II. Discussion

Michael welcomed everyone to the call. The agenda for the call was as follows:

- Welcome and Review of Minutes from May 12-13
- Progress Updates
 - Chapter 1: Research Models
 - Chapter 2: Research Portfolio
 - Chapter 3: Recommendations
 - Framework
 - Innovator
 - Others
- Next Steps/Resources Needed/Work Assignments
- Adjourn

Michael reviewed the minutes from the meeting in May. He felt that valuable outlines were developed for the three chapters at the May meeting.

Chapter 1 Progress Update:

Ken Portier provided an update on progress made on the first chapter regarding funding models. He pointed out that in the minutes from the May meeting the chapter is called Funding Mechanisms and that we agreed that the chapter would discuss classic and newly emerging mechanisms. He listed classic mechanisms – including state models. New and emerging models would include innovative competition and scholar awards, and discussion of other models going on in the pharmaceutical industry.

He pointed out that next, we have a discussion on training, tools, openness, intellectual property, standards-setting, etc that might fit into the barriers section. Part of the introduction would cover how data based on the funding mechanisms reflect the goals of the agencies.

Though the current outline suggests otherwise, Ken did not feel that this chapter would have recommendations. Ken felt that the chapter was developing well and said that he will send around a version that has been reworked to incorporate discussions held at the May meeting and during the call today.

Michael asked how the group felt about training tools. Ken thought we were asking about where training is funded in this process. There are tools for collaboration and also for training. He suggested that we might need a section on tools. Training is done under a variety of tools.

Gayle thought that training would be an important thing to add. There are not enough scientists in this field. Knowing what kind of training mechanisms exist would be helpful. There has been a fairly significant investment in training at least from the DOD perspective.

Cheryl suggested that front end work is needed to raise desirability for going into this field, pointing out that if you build it, they won't necessarily come.

Michael asked the group to discuss pre-doc and post-doc training. Should we have a consistent level of training at both levels?

Cheryl commented that the breast cancer space is crowded, but the environmental space of breast cancer is not crowded. If scientists want to look at environmental causes of breast cancer, there is a whole world of opportunity open to them.

Michael asked Gayle how DOD makes decisions with regard to pre- and post-doc training. She reported that in FY11, the pre-doc program was not offered for the first time in 15 years. She explained that it is really at the post-doc level that individuals focus, go into good labs, and become productive in the area. The post-doc program has been a main-stay and the post-docs seem to be really exceptional.

Ken will make a note to add a bullet point regarding research training (under bullet, highlight pre- and post-doc).

Gayle requested clarification on what is meant by tools. Ken thought that based on his notes that this refers to grants for development of tools in breast cancer and environmental research, rather than grants to do research on environmental factors.

Michael said this could include animal models and computer tools. This would include community-wide integrated databases. Michael suggested to subhead the tools section with experimental models and computer models (with a subhead for databases).

Ken reminded everyone that this chapter is intended to be environment setting for the other chapters. We can go back and say we have funded this in the past and in more recent years have funded databases, etc. Is it time to go back and develop animal models or databases?

Cheryl suggested that we should consider creative and comprehensive ways to compile and advertise training opportunities such as those offered by non-profits and other agencies.

Chapter 2 Progress Update:

Next, Gayle provided an update on chapter 2 regarding the portfolio analysis. Jenny has been working hard on gathering data for the NIH portfolio. She reviewed the following outline:

- A. Introduction
 - 1. Objectives
 - 2. General description of the focus/goal of breast cancer funding by ICs and agencies (focus mainly on DOD and NIH as largest funders)
 - 3. General description of major funding categories by agency
- B. Methodology for identifying relevant funded research
 - 1. Breast cancer research
 - 2. Breast cancer research with an environmental focus
- C. Summary of Findings
 - 1. Federal funding (#,\$,%) for research on breast cancer

2. Federal funding (#,\$,%) for research on breast cancer – broken down by major funding mechanisms
 3. Federal funding for research on breast cancer – broken down by CSO categories (#,\$,%)
 4. Federal funding for research on breast cancer that is related to the environment (#,\$,%)
 5. Federal funding for research on breast cancer that is related to the “environment” – broken down by major funding mechanisms
- D. Discussion
1. Assessment by the Committee of the extent of coverage, pointing out areas that are receiving less funding than expected
 2. Assessment of funding gaps
 3. Assessment of overlaps
 4. Metrics for evaluation
- E. Recommendations
1. Common coding systems with publically available data, such as the CSO , for all agencies (and Institutes within agencies – NCI is the only NIH institute that uses for example)
 2. Others?

The introduction will describe the objectives of the chapter and then provide a general description of the agencies that fund breast cancer research. It will also provide a general description of the major funding categories by agency.

The next section will provide the methodology for narrowing the portfolios (NIH and DOD) down to research with an environmental focus, starting with general breast cancer research. The parameters for the portfolio analysis will be provided here.

Gayle reported that Jenny has finished pulling together the federal funding for NIH. Together with the DOD data, this will be reported in the summary of findings section. The DOD is solely focused on breast cancer so her task was much simpler. The data has been broken down by major funding mechanisms that can go together with Chapter 1. We will use CSO codes to show what was funded according to CSO categories. Then we will narrow down to environment. We will focus on specific CSO codes to capture environmental research. Gayle explained that she expects that there will be differences in how DOD and NIH narrow things down. She did not feel that this was necessarily a bad thing.

Points of discussion included the following:

- 1) Gaps – she didn’t feel like anything was jumping out at her.
- 2) Overlaps – overlaps not necessarily a bad thing.
- 3) Metrics for evaluating research that has been funded.
- 4) Recommendations – this is down the road. Common coding exists between DOD and NCI, not all of NIH.

Gayle reported that we are at the point where data collection is coming to a close. Michael asked whether NIEHS would be willing to add CSO coding. Jenny was not sure. Michael suggested that this might be a recommendation.

Michael asked if this type of coding was available for other diseases/disorders. No one in attendance was aware of similar coding for other diseases.

Michael asked if we should talk about amount of funding and also if so, what we would compare this to. He then asked the group if they felt this area has or has not been underfunded. Gayle suggested that it was unfocused and not concerted. Cheryl argued that there is a huge amount of uncertainty because we just haven't done the research. She used early life exposures and breast cancer risk later in life as an example. There is a vast amount of research that isn't getting done.

Gayle clarified as she explained that she meant that the funding is not being focused on the topic. Cheryl asked what the denominator is. She felt that breast cancer and the environment is extremely underfunded.

From the viewpoint of need, Michael said that it is underfunded.

Michael asked whether we have any idea how much money is going into research based on the systems versus reductionist approach in this area. He felt that this would facilitate the writing of chapter 3. The portfolio analysis group didn't feel that there was a simple way to do this. Nonye suggested that this would require manual effort. Jenny said that specific search terms could be used to do a cursory analysis of the existing dataset, but probably nothing more. The CSO codes do not cover this area. Michael will send some search terms to this group.

The group discussed the assessment of funding gaps and overlaps. Michael felt that in most cases overlaps in research were a positive thing. Ken suggested that we start from the qualitative and then go into the quantitative. We can look at the goals of programs and look for gaps there (qualitative look broadly). Is there less money in some areas versus others? He suggested that we sneak up on it rather than jump in on it.

Sally brought up exposure science as a major gap. There is a huge challenge linking an exposure to an event later life such as cancer. There aren't 50 year old databases on exposures other than lead which isn't relevant to breast cancer. An investment in a national program would benefit many other diseases and disorders, though the funding environment is not amenable to this at this time.

Next the group discussed metrics for evaluation. How do the agencies determine if the research is doing any good? Besides publications, metrics could include whether you are attracting researchers from different disciplines, researchers at different levels of their career, etc. How many things are being identified as causal? We could see what agencies are currently doing first (broadly) and then look at the gaps.

Laura asked some questions from the advocate perspective. What has all of the federal research accomplished? What recommendations from the research can be made to the public?

Ken asked how we can answer the advocate's questions if we as we dig into the data can't even answer the questions. This is a major gap. If you want more of an investment, you need to be able to show what you are getting from the current investment. We need to show what we are getting from the current investment.

This should be driven from an advocate's perspective. Michael wanted to know how agencies are currently looking at how they are doing in this area (breast cancer and environmental research). We could point out that we had to hand-code some of the grants to see what we are doing.

How many concrete recommendations have we been able to provide to the public? Laura said that we don't have the metrics in evaluating the outcomes beyond the traditional ways. In the end this could be a recommendation. The chapter could discuss the traditional methods.

Sally asked where we capture incidence data. Presumably CDC will have something to add to this category. This is not captured in research grants.

Ken pointed out that the research grants have traditional outcomes that can be measures (publications, etc.) and specific outcomes that are unstated – how do these relate to what the public and advocacy groups want to know? The research and the public outcomes do not match up.

Laura said that data on subtypes is not collected by the CDC – they don't look at surveillance in terms of breast cancer subtypes. Effects are being washed out because we are considering all of the different subtypes together.

Michael requested that Jenny confirm that the SOS group is covering subtypes. Jenny will communicate that we are expecting this from them. The genetics people are thinking about subtypes, so there is no reason why the environmental research cannot do the same thing. If this is a gap then we can identify for future funding.

The group felt that a heading is needed in the chapter to cover evaluation metrics.

Chapter 3 Progress Update:

Michael led the discussion on the last chapter. At the May meeting we decided that this chapter would cover recommendations. The slides presented were the ones that were presented at the May meeting. The discussion in May morphed into the idea of a “framework”. Michael thinks of the framework as he does proteins with structured and unstructured areas. He proposed that in the framework, there would be quantitatively structured areas and less structured qualitative areas that would signify areas where funding is needed.

Gayle thought it would be helpful to have a diagram of what we were envisioning – even if it were rough. The graphics staff at NIEHS could help us develop. Michael will sketch something and send it to Jenny.

Ken thought that we are missing something about communicating the complexity to the public. We have to be able to communicate better where we are in our knowledge on this problem. The only way is to develop the systems models.

Laura said that the public wants the simple answers. She agreed that we should try and communicate the complexity. Michael agreed and commented that people expect the smoking gun.

Cheryl was asked by Michael to make a list of the “grand challenges” including exposure science, mixtures, etc.

Sally wondered if we need some social science research in these types of questions (breast cancer and environmental research). What does public need that will motivate them to act?

Michael asked what does the public want to know and if we gave it to them, how would they use it?

Gayle asked the group if they were aware of similar models in existence for other diseases and disorders. Michael was sure that we were not the first ones to think about this. The idea of going beyond systems approaches to more of a qualitative approach might be new.

Sally said that people are talking about obesity, asthma, etc. She sent the foresight.pdf document previously that demonstrates the complexity of such a model.

Sally said that we should build in that the framework is not a static thing that will continue to be adjusted and will evolve.

Cheryl was unclear how it will fit into the document. Michael said that it will be a recommendation.

We should talk about whether the innovator/Howard Hughes model is a good model and whether it should be adapted by NIH.

Laura asked whether we had looked at the Faster Cures model. They are bringing advocates, industry, scientists, and venture capitalists to the table. She encouraged the group to visit fastercures.org for more information.

Ken had some of those on his slide (MS model, etc.). He commented that these were more collaboration models to produce win-win scenarios to move things faster than normal competition. These models will overcome challenges such as intellectual property issues, etc. that tend to keep researchers in their silos.

Cheryl suggested that have collaborative models as their own heading.

Laura suggested that we come up with our own model as a hybrid. We need to have advocates in the picture. Michael asked Laura to take a stab at writing a paragraph describing this type of model.

This work will prepare this group for making recommendations. This will be discussed at the next meeting. We need to understand these ideas better – such as the NSF Ideas Lab. Maybe someone can circulate a paragraph on this model.

Ken asked that we back up the conversation to the systems approach model. Someone asked the question – what would we do with this? One of the things not captured is the idea of being able to in more detail code current and future research efforts so we know what part of the system those efforts are addressing. So that when we do a broader gap analysis later on those gaps can be against our system understanding not just against just broad areas of whether we are doing research in prevention. We can understand certain components of the linkage model. The coding concept is not really in here prominently.

Cheryl mentioned that Varmus's Grand Challenges were issued in 2003. Michael said we might need something a little more current.

Michael said that we should move the chapters into text so that we have something to share with the committee by mid-summer.

The next meeting (conference call) is on August 16. Michael suggested that the first two chapters be written up by August 14 so that they could be discussed on the next call.

The last chapter will be more developed (Ken and Cheryl). Michael requested that Jenny arrange a conference call for this purpose. In August they will be present a more developed outline to this group.

Cheryl asked the group if there were other perceived grand challenges beyond exposure assessment, mixtures, and systems biology. As people think of them, they will send to Cheryl.

Ken said that one other challenge is getting the public to understand what the science shows and doesn't show. The public looks for simple messages in a very complex environment. Again, Laura encouraged us to address the different subtypes of cancer. Cheryl will add these to her list.

III. Action Items (due August 14)

- Ken will add a bullet point regarding research training (under bullet, highlight pre- and post-doc) to the outline for Chapter 1.
- Michael will send the portfolio analysis group some search terms for "systems biology" for their analysis.
- Jenny will confirm that the SOS group is covering subtypes. Jenny will communicate that we are expecting this from them.
- Gayle thought it would be helpful to have a diagram of what we were envisioning with regard to the framework – even if it were rough. Michael will sketch something and send it to Jenny.
- Cheryl will make a list of the "grand challenges" including exposure science, mixtures, etc.
- Laura suggested that we come up with our own model as a hybrid. We need to have advocates in the picture. Laura will write a paragraph describing this type of model.
- The first two chapters will be drafted and distributed to the RP subcommittee by August 14 and discussed on that call.
- The outline for the last chapter will be more developed by Ken, Cheryl, and Michael. Jenny will arrange a conference call for this purpose. The outline will be presented on the August 16 call.
- Subcommittee members will send Cheryl any additional "grand challenges" to her not mentioned on the call today.

IV. Adjournment

The meeting was adjourned at 2:30 p.m. on June 20, 2011.

CERTIFICATION

I hereby certify that, to the best of my knowledge, the foregoing minutes and attachments are accurate and complete.

/Michael Gould/

Michael Gould, PhD

Chairperson

Research Process Subcommittee

Interagency Breast Cancer & Environmental Research Coordinating Committee

/Gwen W. Collman/

Gwen W. Collman, PhD
Executive Secretary
Research Process Subcommittee
Interagency Breast Cancer & Environmental Research Coordinating Committee

Proper signatures
Treat as signed, § 1.4(d)(2)